14th meeting of the PSN IUCLID sub-group
04 Nov 2025

IUCLID REPORT GENERATOR

IDATA, PREV

EUROPEAN FOOD SAFETY AUTHORITY

OUTLINE

"IUCLID REPORT GENERATOR IS CONTINUOSLY IMPROVED"

1. **Updates to existing reports**
   - General enhancements and bug fixes
   - Tox/Ecotox for chemicals
   - Reports for microorganisms
   - MRL report
2. **New reports:** 4 – Confidential information
3. **Ongoing and future work**

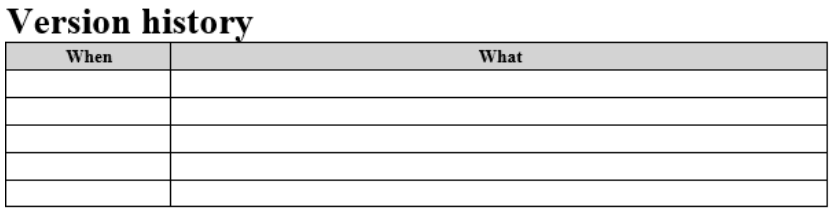
UPDATES TO EXISTING REPORTS

#OpenEFSA

UPDATES TO EXISTING REPORTS: ENHANCEMENTS AND BUGS

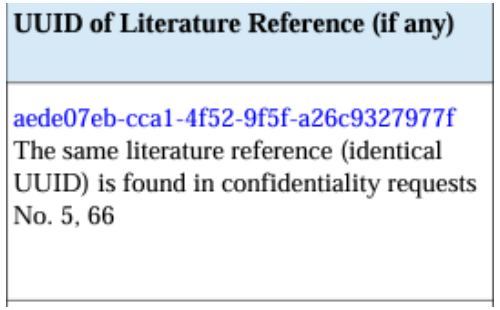
Enhancements:

- **Version history** table added to all Vol3 and MRL reports



- **GAP** table:
  - Sorted alphabetically by crop (per product)
  - Rephrasing for witholding and waiting periods
- Non-confidential **attachment metadata** printed for all **summaries** (as done already for study records)

- Restructuring of **literature search** paragraph in Vol3 reports
- List of **confidentiality claims**: added information on repeated literature reference UUIDs in the table



Bugs identified in Identity, Ecotox, Residues and MRL reports have been fixed

All changes are available in the **October release** (Zenodo publication will follow)

UPDATES TO EXISTING REPORTS: TOX / ECOTOX FOR CHEMICALS

ICPS (Italy) is revising and proposing enhancements to Vol 3 reports for Tox and Ecotox for chemiclas (both a.s. and product, see slides 12th PSN):

- Changes implemented (available in the October release):
  - Re-design of Ecotox product risk assessment section, with inclusion of additional info such as the RAC values (from both product and a.s. levels), PECsw and PEC sediment.
  - Addition of Biological Activity of Metabolites Potentially Occurring in Groundwater section (Ecotox a.s.).
  - Dynamic appearance of non-frequent sections (e.g. Monitoring Data) according to actual content provided in dossier.
  - Tabularization of several Tox methods and results (e.g. Skin Sensitisation, Eye/Skin Irritation, Dose/Concentrations).
  - Cleaner display of worker/operator/bystander exposure scenarios.
- Under development:
  - New ecotox results section layout (Effect Levels and Dose Response tables).
  - New tox summary tables listing key studies attributes within sections (as already done for Ecotox).
- Several format changes proposed for April 2026 release

UPDATES TO EXISTING REPORTS: MICROORGANISMS

ICPS (Italy) is revising and proposing the format for Vol 3 reports for **microbial active substances**, based on the EC templates recently endorsed at the PAFF (see slides 12th PSN):

- **1st batch** of reports revised by July 2025: Biological properties, Tox and Ecotox sections
  - **"3 – Active Substance B-2 (BioProperties)"**
    - Significant format changes proposed for the FLEXIBLE_RECORD.BioPropertiesMicro (mostly to allow linking full studies and not just references) + a new ENDPOINT_STUDY_RECORD
    - If accepted, report to be revised by April 2026 release

UPDATES TO EXISTING REPORTS: MICROORGANISMS

ICPS (Italy) is revising and proposing the format for Vol 3 reports for **microbial active substances**, based on the EC templates recently endorsed at the PAFF (see slides 12th PSN):

- **1st batch** of reports revised by July 2025: Biological properties, Tox and Ecotox sections
  - **"3 – Active Substance B-6 (Tox)"**
    - Main changes already implemented, available in the October release:
      - **ToC aligned** with the official template
        - Note: a minor change in the IUCLID ToC is proposed for April 2026, affecting points 5.3.1.3 and 5.4 – the reports are already aligned with this
      - FLEXIBLE_SUMMARY.PathogenicityInfectivityHumans (previously missing) printed in **section 5.2**
      - Toxicity studies on **metabolites**:
        - FLEXIBLE_SUMMARY.InformationToxicityMetabolites (previously missing) printed in **section 5.5.1**
        - Any **datasets on metabolites** printed in **5.5.2**
        - Any **datasets on relevant impurities** printed in **5.5.3** (subsection appears only if there is content)
    - Format changes have been proposed for 2026 – if accepted, the report will be revised by April 2026

UPDATES TO EXISTING REPORTS: MICROORGANISMS

ICPS (Italy) is revising and proposing the format for Vol 3 reports for **microbial active substances**, based on the EC templates recently endorsed at the PAFF (see slides 12th PSN):

- **1st batch** of reports revised by July 2025: Biological properties, Tox and Ecotox sections
  - **"3 – Active Substance B-9 (Ecotox)"**
    - Main changes already implemented, available in the October release:
      - **ToC aligned** with the official template
      - Toxicity studies on **metabolites** (same approach as for Tox)
        - FLEXIBLE_SUMMARY.InformationEcotoxicityMetabolites (previously missing) printed in **section 8.8.1**
        - Any **datasets on metabolites** printed in **8.8.2**
        - Any **datasets on relevant impurities** printed in **8.8.3** (subsection appears only if there is content)
    - Format changes have been proposed for 2026 – if accepted, the report will be revised by April 2026

UPDATES TO EXISTING REPORTS: MICROORGANISMS

ICPS (Italy) is revising and proposing the format for Vol 3 reports for **microbial active substances**, based on the EC templates recently endorsed at the PAFF (see slides 12th PSN):

- **1st batch** of reports revised by July 2025: Biological properties, Tox and Ecotox sections
- **2nd batch** of reports revised by November 2025: Identity, Further Information, Analytical Methods, Fate and Residues
  - Currently under analysis
  - Reports to be adapted by April 2026
  - If format changes needed, they will be proposed 2027 and implemented in the reports

UPDATES TO EXISTING REPORTS: MICROORGANISMS

In parallel to the proposals from ICPS for microbial active substance reports, the **Tox and Ecotox sections for the product** have been revised and aligned to the extent possible with the official templates:

- **“3 – Product B-6 (Tox)”**
  - **ToC aligned** with the official template
    - Note: potential modification of the IUCLID ToC to include a document for section 7.4 Additional toxicity information (currently only a cross-reference exists)
  - FLEXIBLE_SUMMARY.AssessmentOfPotentialToxicity (previously missing) printed in **section 7.2**
  - Data on **safeners and synergists**, if any, printed in **section 7.6**

- **“3 – Product B-8 (Ecotox)”**
  - **ToC aligned** with the official template

UPDATES TO EXISTING REPORTS: MRL

- With IUCLID 2025 April release (IUCLID6 v9), significant changes were introduced in endpoint/flexible summaries of the residues section

- The FTL templates for the MRL report and the Vol3 Residues report were thus adapted accordingly:
  - New summary tables are created for some of the sections, combining data from several documents (of same type) and different repeatable blocks
  - Their format is also aligned with the official template for the List of Endpoints
  - For these tables to be successfully compiled, data needs to be entered in the dossier following instructions in the manuals
- A mapping file will be published in Zenodo after the October release clarifying how these tables are generated
- In the following slides we illustrate a couple of examples

UPDATES TO EXISTING REPORTS: MRL – MAGNITUDE RESIDUES IN PLANTS

- The report works with the new formats (May 2025 release) fulfilled according to the 2025 user manual
- It provides a single summary table of residue trials and derived endpoints
- It merges all EP summaries for primary crops and all summaries for rotational crops, separately.
- It separates the results per residue definitions
- All data related to the same GAP are merged on the same line (however trials with no matching GAP are not reported)
- Extrapolations: if the same GAP is supported for 2 crops and the same MRL is derived, create a unique GAP for both crops and refer all trials and endpoints to it (commodity on which trials are performed can be specified).
- Combined NEU/SEU data sets: create an additional single GAP for N/S, refer the combined endpoints to this GAP and add remark (based on combined N/S data).

Endpoint
residues in crops (field trials)
Residue definition monitoring
RD-Mo
Residue definition Risk Assessment
RD-RA

Relevant GAPs + New item | Import file

	GAP name
1	GAP1-WheatNE
2	GAP2-WheatSE

Summary of key residues data selected from the supervised residue trials + New item | Import file

	Commodity	Relevant GAP	Residue level: RD Mo	Residue level: RD RA	Plant back interval (PBI)	Study name / type
1	0500090 - Wheat (0500000 - Cereals > 0500090 - Wheat)	GAP1-WheatNE	0.5 mg/kg	0.7 mg/kg		2021_magnitude of residues_wheat_Northern Europe_01 | experimental study | 1 (reliable without restriction) | quantifiable residues expected in crop commodities
2	0500090 - Wheat (0500000 - Cereals > 0500090 - Wheat)	GAP1-WheatNE	0.4 mg/kg	0.6 mg/kg		2021_magnitude of residues_wheat_Northern Europe_02 | experimental study | 1 (reliable without restriction) | quantifiable residues expected in crop commodities

Endpoints derived from key residue data + New item | Import file

	Commodity	Relevant GAP	Highest residue RD-RA	STMR RD-RA	Highest residue RD-Mo	STMR RD-Mo	Plant back interval (PBI)	Conversion factor	MRL derived
1	0500090 - Wheat (0500000 - Cereals > 0500090 - Wheat)	GAP1-WheatNE	0.5 mg/kg	0.02 mg/kg	0.7 mg/kg	0.03 mg/kg		1	0.5 mg/kg

Summary of key residues data selected from the supervised residue trials

New item | Import file

	Commodity	Relevant GAP	Residue level: RD Mo	Residue level: RD RA	Plant back interval (PBI)	Study name / type	Remark
1	0500090 - Wheat (0500000 - Cereals > 0500090 - Wheat)	GAP1-WheatNE	1 mg/kg	1.5 mg/kg			
2	0500090 - Wheat (0500000 - Cereals > 0500090 - Wheat)	GAP1-WheatNE	2 mg/kg	2.8 mg/kg			
3	0500090 - Wheat (0500000 - Cereals > 0500090 - Wheat)	GAP1-WheatNE	3 mg/kg	3.9 mg/kg			
4	0500090 - Wheat (0500000 - Cereals > 0500090 - Wheat)	GAP1-WheatNE	4 mg/kg	5.1 mg/kg			
5	0500070 - Rye (0500000 - Cereals > 0500070 - Rye)	GAP1-WheatNE	5 mg/kg	6.6 mg/kg			
6	0500070 - Rye (0500000 - Cereals > 0500070 - Rye)	GAP1-WheatNE	6 mg/kg	7.8 mg/kg			
7	0500070 - Rye (0500000 - Cereals > 0500070 - Rye)	GAP1-WheatNE	7 mg/kg	8.9 mg/kg			
8	0500070 - Rye (0500000 - Cereals > 0500070 - Rye)	GAP1-WheatNE	8 mg/kg	9.5 mg/kg			

Variability factors

New item | Import file

Commodity	Relevant GAP	Variability factor	Residue definition	Study name / type
No data added				

Endpoints derived from key residue data

New item | Import file

	Commodity	Relevant GAP	Highest residue RD-RA	STMR RD-RA	Highest residue RD-Mo	STMR RD-Mo	Plant back interval (PBI)	Conversion factor	MRL derived	MRL at LOQ	MRL is provisional	Remarks
1	0500090 - Wheat (0500000 - Cereals > 0500090 - Wheat)	GAP1-WheatNE	9.5 mg/kg	5.8 mg/kg	8 mg/kg	4.5 mg/kg			15 mg/kg	☐		Combined data set wheat (4) and rye (4)

TIPS: The region (NEU/SEU) is taken from the GAP table (if the name reported in the field "relevant GAP"is exactly the same!)

Commodity	Region/ Indoor	Residue levels observed in the supervised residue trials (mg/kg)	Calculated MRL (mg/kg)	HR (mg/kg)	STMR (mg/kg)	CF	Remarks
Residue definition for monitoring: RD-Mo, **Residue definition for risk assessment:** RD-RA							
0500090 - Wheat	NEU	- Mo: 1, 2, 3, 4, 5, 6, 7, 8 - RA: 1.5, 2.8, 3.9, 5.1, 6.6, 7.8, 8.9, 9.5	15	- Mo: 8 - RA: 9.5	- Mo: 4.5 - RA: 5.8		Endpoint derived for GAP1-WheatNE Combined data set wheat (4) and rye (4) Used in the residue trials: 0500090 - Wheat, 0500070 - Rye

UPDATES TO EXISTING REPORTS: MRL – DIETARY BURDEN

1
RD RA (plant/feed)
Rd-RA plant
Animal species
1.1. Beef (1. Cattle > 1.1. Beef)
Median dietary burden
0.0093 mg/kg bw per day
Maximal dietary burden
0.017 mg/kg bw per day
Median dietary burden
0.39 mg/kg dry matter
Maximal dietary burden
0.72 mg/kg dry matter
Trigger exceeded?
yes
Remarks

2
RD RA (plant/feed)
Rd-RA plant
Animal species
1.2. Dairy (1. Cattle > 1.2. Dairy)
Median dietary burden
0.0143 mg/kg bw per day
Maximal dietary burden
0.027 mg/kg bw per day
Median dietary burden
0.37 mg/kg dry matter
Maximal dietary burden
0.7 mg/kg dry matter
Trigger exceeded?
yes
Remarks

3
RD RA (plant/feed)
Rd-RA plant
Animal species
2.1. Ram/ewe (2. Sheep > 2.1. Ram/ewe)
Median dietary burden
0.0171 mg/kg bw per day
Maximal dietary burden
0.039 mg/kg bw per day
Median dietary burden
0.51 mg/kg dry matter
Maximal dietary burden
1.2 mg/kg dry ma
Trigger exceeded?
yes
Remarks

4
RD RA (plant/feed)
Rd-RA plant
Animal species
2.2. Lamb (2. Sheep > 2.2. Lamb)
Median dietary burden
0.0225 mg/kg bw per day
Maximal dietary burden
0.045 mg/kg bw per day
Median dietary burden
0.53 mg/kg dry matter
Maximal dietary burden
1.06 mg/kg dry matter
Trigger exceeded?
yes
Remarks

- *Blue values* are "calculated" by the report
- For cattle (all), it takes the highest DB between beef and dairy, based on mg/kg bw per day (Max) and report the corresponding name and values in the whole line
- For sheep (all), it takes the highest DB between Ram/Ewe and Lamb, based on mg/kg bw per day (Max) and report the corresponding names and values in the whole line

Table B.7.3.

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup *(a)*	Most critical commodity *(b)*	Trigger exceeded (yes/no)	Comments
	mg/kg bw per day		mg/kg DM					
	Median	Max	Median	Max				
Residue definition for risk assessment: Rd-RA plant								
Cattle (all)	*0.0143*	*0.027*	*0.39*	*0.72*	*Dairy*		*yes*	
Cattle (dairy)	0.0143	0.027	0.37	0.7			yes	
Sheep (all)	*0.0225*	*0.045*	*0.53*	*1.2*	*Lamb*		*yes*	
Sheep (ram/ewe)	0.0171	0.039	0.51	1.2			yes	

NEW REPORTS: “4 – CONFIDENTIAL INFORMATION”

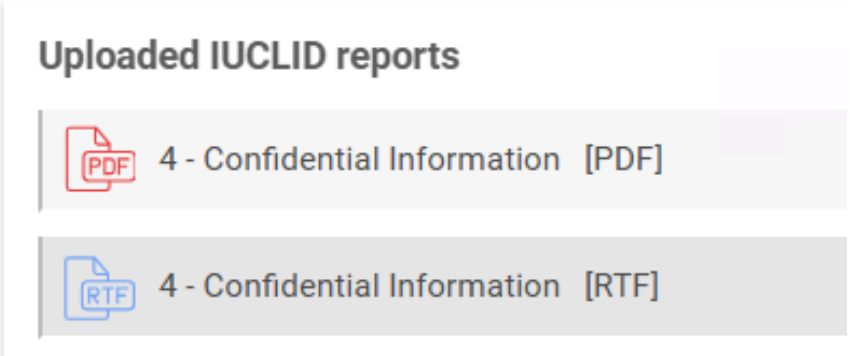
NEW REPORT: “4 – CONFIDENTIAL INFORMATION”

- A new report “***4 – Confidential Information***” is under development in order to extract data from IUCLID that was previously provided as part of Document J:
  - Reminder:
    - **Document J has been dismissed** as from **IUCLID6 v9** for **new chemical** PPP **applications**
    - Applicants need to follow indications included in:
      - Doc J removal - instructions for applicants on data reporting in IUCLID
      - the latest Active substance application manual

      which are considered to build the report
  - The new report is to be used by:
    - **applicants**: to ensure that all **required data** to which confidentiality can be claimed is **entered as expected** in the IUCLID dossier before submission
    - by **RMS**: to support the **preparation of the DAR/RAR Volume 4**

NEW REPORT: “4 – CONFIDENTIAL INFORMATION”

- A first **draft version of the report** was finalised at the end of summer and can be found in **IUCLID Beta and Agency**



- A **Working Party** has been formed to test and provide feedback on this new report:
  - 1st meeting – October 1st: kick-off, presentation of the report and initial feedback
  - 2nd meeting – November 14: to present and discuss the feedback collected
  - 3rd meeting – December: to conclude on feedback and amendments for the report

- The **final version** of the report is to be delivered in **April 2026**
  - if additional format changes in IUCLID are required, the report might need to be amended again in 2027

ONGOING AND FUTURE WORK

UPDATES AND ONGOING WORK

Report	Updates / comments	Status	Estimated deadline
1 – Overall conclusions	• Improved CLH report released with IUCLID 6 version 9.0.1 (27th of May 2025) • To be adapted by EFSA to create the "1 – Overall conclusions" report, aligned with DAR Vol1	In development	~~End of 2025~~ **2026**
2 – List of references	• Format change proposed to include Vertebrate Y/N information in IUCLID – if accepted, report will be amended for 2026 April release	Under revision	Q2 2026
3 – Active Substance / Product B-1 (Identity)	• Revised by ICPS for microorganisms a.s. (see slides before)	Finished (chem) Under revision (micro)	- Q2 2026
3 – Active Substance / Product B-2 (PhysChem)		Finished	-
3 – Biological Properties	• Revised by ICPS and format changes proposed for 2026 April release	Under revision	Q2 2026
3 – Active Substance / Product B-3 (Application)		Finished	-
3 – Active Substance / Product B-4 (FurtherInfo)	• Revised by ICPS for microorganism a.s.	Finished (chem) Under revision (micro)	- Q2 2026

UPDATES AND ONGOING WORK

Report	Updates / comments	Status	Estimated deadline
3 – Active Substance / Product B-5 (AnMethods)	• Revised by ICPS for microorganism a.s.	Finished (chem) Under revision (micro)	- Q2 2026
3 – Active Substance / Product B-6 (Tox)	• Revised by ICPS	Under revision (chem) Finished (micro)	Q2 2026 _
3 – Active Substance B-7 (Residues)	• Revised by ICPS for microorganisms	Finished (chem) Under revision (micro)	- Q2 2026
3 – Active Substance / Product B-8 (Fate)	• Revised by ICPS for microorganisms	Finished (chem) Under revision (micro)	- Q2 2026
3 – Active Substance / Product B-9 (Ecotox)	• Revised by ICPS	Under revision (chem) Finished (micro)	Q2 2026 -
Literature Search (Active Substance / Product)	• Format changes proposed to distinguish searches by section → from April 2026, searches could be included in Vol3 reports and this report could be deprecated (to be discussed)	Finished (TBD)	-

UPDATES AND ONGOING WORK

Report	Updates / comments	Status	Estimated deadline
4 – Confidential Information	• Report already developed, being tested by the WP on the Confidential Information report • Proposed improvements to be implemented latest by next April release (depending on complexity)	Testing	Q2 2026
List of Endpoints (LoE)	• New section 3 on residues available • Work to be continued with Ecotox and Fate sections	In development	~~Q4 2025~~ **2026**
MRL report	• Testing phase ended on July 2025 – proposals for improvements being discussed and some already under implementation	Under revision	Q2 2026
Residue trials	• Separate reports in CSV will be prepared for primary crops, rotational crops and processed commodities, extracting data from the new methods and results blocks introduced in endpoint study records in IUCLID6 v9 (May 2025)	Under analysis	Q2 2026

POTENTIAL IUCLID REPORTING WORKSHOP IN 2026

- ECHA and EFSA are collecting ideas and feedback from IUCLID users to explore if a **IUCLID Reporting Workshop** should be held in 2026.
  - Two such events were held previously (2022/2023)
  - Since then, there has been new developments in generating reports in a Docx format, as well as updates to existing reports maintained by ECHA and EFSA.

- A survey has been prepared and is being circulated: https://ec.europa.eu/eusurvey/runner/dafcf3ca-2598-c50b-dbee-df540dd51f50
  - We will circulate it in the PSN IUCLID Teams channel shortly

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